## IN THE CLAIMS

- 1. (withdrawn) A method of increasing viscosity of a pharmaceutical formulation for oral or topical administration comprises the steps of combining:
- a. an effective amount of one or more hydrophobic active ingredients:
- b. 5 to 50% of one or more compounds selected from polyglycerol esters of fatty acids of formula (1)

 $\text{CH}_2\text{OR-CHOR-CH}_2\text{O-}[\text{CH}_2\text{CHOR-CH}_2\text{O-}]_N\text{CH}_2\text{-CHOR-CH}_2\text{OR} \qquad (1)$  wherein n is an integer from 4 to 13 and R is H or CO.R' wherein r" is  $\text{C}_{8-22}$  saturated, unsaturated or hydroxylated alkyl and wherein at least one group R is not hydrogen:

c. 5 to 50% of one or more compounds selected from polyglycerol esters of fatty acids and/or unsaturated fatty acids of formula (2)

- d. 5 to 50% of one or more compounds selected from triglyceride macrogol glycerol esters, partial glycerides or fatty acids or macrogol esters of fatty acids in which the average quantity of reacted ethylene oxide in the synthesis of these substances ranges between 50 to 150 mols and concurrently the ratio between components b) and d) is from 0.1:1 to 10:1; wherein the above percentages are selected to total 100%; and wherein upon dilution with water 1:1 by volume the viscosity of the formulation increases by at least 5 times in comparison to the undiluted composition.
- 2. (currently amended) A pharmaceutical formulation for oral or topical administration comprising:
- a. 0.1 to 30.0% by weight of one or more hydrophobic active ingredients;

b. 0.1 to 60.0% by weight of one or more gelators comprising polyglycerol esters of fatty acids of formula (1)

CH<sub>2</sub>OR-CHOR-CH<sub>2</sub>O-[CH<sub>2</sub>CHOR-CH<sub>2</sub>O-]<sub>N</sub>CH<sub>2</sub>-CHOR-CH<sub>2</sub>OR (1) wherein N-N is an integer from 4 to 13 and R is H or CO.R' wherein R' is  $C_{6-22}$  saturated, unsaturated or hydroxylated alkyl and wherein at least one group R is not hydrogen, having an HLB value not less than 10;

- c. 0.1 to 60.0% by weight of one or more gel-crating substances selected from polyglycerol-3-esters of oleate acid, having an HLB value not greater than 9; and
- d. 1.0 to 60% by weight of one or more co-gelator substances selected from the group consisting of triglyceride macrogol glycerol esters, partial glycerides or fatty acids or macrogol esters of fatty acids in which the average quantity of reacted ethylene oxide in the synthesis of these substances ranges between 50 to 150 mols and concurrently the ratio between components b) and d) is from 0.1:1 to 10:1;

## e.5.0 to 30% by weight of one or more C2 to C4 alcohols;

wherein the above percentages are selected to total 100%; and wherein upon dilution with water 1:1 by volume the viscosity of the formulation forms a dispersion of polymorphous gel particles having a dimension of 0.2 to 500µm increases by at least 5 times in comparison to the undiluted composition.

- 3. (withdrawn) A pharmaceutical formulation for oral or topical administration including:
- a. 0.1 to 30.0% of one or more hydrophobic active ingredients;
- b. 0.1 to 60.0% of one or more gelators comprising fatty acid esters of polyglycerol;
- c. 0.1 to 60.0% of one or more gel-creating substances selected from esters of polyglycerol with fatty acids and/or unsaturated fatty alcohols;

Application No.: 09/642,242

- d. 1.0 to 60% of one or more co-gelator substances selected from macrogolglycerol esters of fatty acids, macrogolglycerol esters of vegetable oils, macrogolesters of fatty acids, mono- and di- macrogolesters of mono-, di- and tri-acylglycerols;
- e. 5.0 to 30% of one or more  $C_2$  to  $C_4$  alcohols; wherein the above percentages are selected to total 100%; and wherein upon dilution with water the formulation forms a dispersion of polymorphous gel particles having a dimension of 0.2 to 500  $\mu m$ .
- 4. (withdrawn) A method of pharmaceutical formulation as claimed in claim 3, wherein the ratio of a:c and/or a:e is in the range 0.001:1 to 10:1.
- 5. (original) A formulation as claimed in claim 3, wherein component b) is selected from polyglycerol esters of fatty acids of formula (1)

- 6. (withdrawn) A method as claimed in claim 1, wherein R' is  $C_{16-18}$  saturated or unsaturated alkyl.
- 7. (original) A formulation as claimed in claim 5, wherein R' is  $C_{16-18}$  saturated or unsaturated alkyl.
- 8. (withdrawn) A method as claimed in claim 6, wherein R is selected from the group consisting of oleate, linoleate stearate, linolate, myristate, laurate and mixtures thereof.
- 9. (withdrawn) A formulation as claimed in claim 7, wherein R is selected from the group consisting of oleates, linoleate stearate, linolate, myristate, laurate and mixtures thereof.
- 10. (withdrawn) A method as claimed in claim 8, wherein component b) is selected from polyglyceryl-10-esters of fatty acids.

- (withdrawn) A formulation as claimed in claim 3, wherein component b) is selected from polyglyceryl-10-esters of fatty acids.
- 12. (withdrawn) A formulation as claimed in claim 3, wherein component c) is selected from polyglycerol esters of fatty acids and/or unsaturated fatty acids of formula (2)

CH<sub>2</sub>OR-CHOR-CH<sub>2</sub>O-[CH<sub>2</sub>CHOR-CH<sub>2</sub>O]<sub>N</sub>CH<sub>2</sub>-CHOR-CH<sub>2</sub>OR (2) wherein n is an integer from 0-10 and R=H or CO.R" wherein R" is C<sub>8-22</sub> saturated, unsaturated or hydroxylated alkyl, and wherein while at least one group R is not hydrogen.

- 13. (withdrawn) A method as claimed in claim 1, wherein R" is  $C_{16-18}$  saturated or unsaturated alkyl.
- (withdrawn) A formulation as claimed in claim 12, wherein R" is  $C_{16-18}$  saturated or unsaturated alkyl.
- (withdrawn) A method as claimed in claim 13, wherein R is from the group consisting of oleate, linoleate, selected stearate, isostearate, linolate, myristate, laurate and mixtures thereof.
- 16. (withdrawn) A formulation as claimed in claim 14, wherein R is selected from the group consisting of oleate, linoleate, stearate, isostearate, linolate, myristate, laurate and mixtures thereof.
- 17. (withdrawn) A method as claimed in claim 1, component c) is selected from polyglyceryl-3-esters of oleic acid.
- 18. (withdrawn) A formulation as claimed in any of claim 12, wherein component c) is selected from polyglyceryl-3-esters of oleic acid.
- 19. (withdrawn) A formulation as claimed in claim 3, wherein component d) is selected from triglyceride macrogol glycerol esters, partial glycerides or fatty acids or macrogol esters of fatty acids in which the average quantity of reacted ethylene oxide in the synthesis of these substances range between 50 to

- 150 mols and concurrently the ratio between components b) and d) is from 0.1:1 to 10:1.
- 20. (withdrawn) A method as claimed in claim 1, wherein component d) is macrogol glycol halogenated castor oil.
- 21. (withdrawn) A formulation as claimed in claim 3, wherein component d) is macrogol glycerol halogenated castor oil.
- 22. (withdrawn) A method as claimed in claim 1, wherein component b) is selected from polyglyceryl-10-esters of oleic acid; component c) is selected from polyglyceryl-3-esters of oleic acid; and component d) is macrogol(1760) glycerol hydrogenated castor oil.
- 23. (withdrawn) A formulation as claimed in claim 3, wherein component b) is selected from polyglycerol-10-esters of oleic acid; component c) is selected from polyglyceryl-3-esters of oleic acid; and component d) is macrogol(1760) glycerol hydrogenated castor oil.
- 24. (withdrawn) A method as claimed in claim 1, wherein the component a) is selected from cyclosporins especially cyclosporin A, cyclosporin D or cyclosporin G, wherein the ratio of components a:c+e is 1.001:1 to 1.5:1.
- 25. (currently amended) A formulation as claimed in any preceding according to claim 2, wherein component a) is selected from cyclosporins especially cyclosporin A, cyclosporin D or cyclosporin G, wherein the ratio of components a:c+e is 1.001:1 to 1.5:1.
- 26. (withdrawn) A method as claimed in claim 1, wherein component a) is selected from taxanes, especially docataxel or paclitaxel, wherein the ratio between components a:c+e is 0.001:1 to 1.5:1.
- 27. (currently amended) A formulation as claimed in any preceding according to claim 2, wherein component a) is selected from taxanes, especially docataxel or paclitaxel, wherein the ratio between components a:c+c is 0.001:1 to 1.5:1.

- 28. (withdrawn) A method as claimed in claim 1, wherein component a) includes at least one substance selected from the group comprising cyclosporins and at least one substance selected from the group comprising taxanes.
- 29. (currently amended) A formulation as claimed in any preceding according to claim 2, wherein component a) includes at least one substance selected from the group comprising cyclosporins and at least one substance selected from the group comprising taxanes.
- 30. (withdrawn) A formulation as claimed in any claim 2, further including excipients to modify the physical, chemical, microbial stability, organoleptic or physical processing properties of the formulation.
- 31. cancelled.
- 32. (withdrawn) A pharmaceutical dosage form comprising a gelatin capsule containing a formulation as claimed in claim 3.
- 33. (withdrawn) A pharmaceutical dosage form comprising a formulation of claim 2 in combination with a pharmaceutically acceptable excipient, wherein the dosage form is a liquid dosage form.
- 34. (withdrawn) A pharmaceutical dosage form comprising a formulation of claim 2 in combination with a pharmaceutically acceptable excipient, wherein the dosage form is a gelatine capsule.
- 35. (withdrawn) A pharmaceutical formulation as claimed in claim 2, wherein the ratio of a:c and/or a:e is in the range 0.001:1 to 10:1.
- 36. (withdrawn) A formulation as claimed in claim 2, wherein R' is  $C_{16-18}$  saturated or unsaturated alkyl.
- 37. (withdrawn) A formulation as claimed in claim 2, wherein R' is selected from the group consisting of oleates, linoleate stearate, linolate, myristate, laurate and mixtures thereof.

Application No.: 09/642,242 Docket No.: TEVGAL 3.0-175

- (withdrawn) A formulation as claimed in claim 2, wherein component b) is selected from polyglyceryl-10-esters of fatty acids.
- 39. (withdrawn) A formulation as claimed in any preceding claim, wherein component d) is macrogol glycol hydrogenated castor oil.
- 40. (withdrawn) A formulation as claimed in any preceding claim, wherein component b) is selected from polyglyceryl-10oleic acid; component c) is selected from of polyglyceryl-3-esters of oleic acid; and component d) macrogol (1760) glycerol hydrogenated castor oil.
- (withdrawn) A formulation as claimed in any preceding claim, further comprising excipients to modify the physical, microbial stability, organoleptic or physical chemical, processing properties of the formulation.
- 42. (withdrawn) A method of making a pharmaceutical formulation for oral or topical administration comprising:
- 0.1 to 30.0% of one or more hydrophobic active ingredients;
- 0.1 to 60.0% of one or more gelators comprising polyglycerol esters of fatty acids of formula (1)
- CH2OR-CHOR-CH2O-[CH2CHOR-CH2O-]NCH2-CHOR-CH2OR (1);wherein n is an integer from 4 to 13 and R is H or CO.R' wherein is  $C_{8-22}$  saturated, unsaturated or hydroxylated alkyl and wherein at least one group R is not hydrogen;
- 0.1 to 60.0% of one or more gel-creating substances selected from polyglyceryl-3-esters of oleic acid, having an HLB value not greater than 9;
- 1.0 to 60% of one or more co-gelator substances selected from the group consisting of triglyceride macrogol glycerol esters, partial glycerides of fatty acids and macrogol esters of fatty acids in which the average quantity of reacted ethylene oxide in the synthesis of the substances ranges between

50 to 150 mols and concurrently the ratio between components b) and d) is from 0.1:1 to 10:1;

- e. 5.0 to 30% of one or more C2 to C4 alcohols; wherein the above percentages are selected total 100%; and wherein upon dilution with water the formulation forms a dispersion of polymorphous gel particles having a dimension of 0.2 to 500µm.
- 43. (withdrawn) A method as claimed in claim 42, wherein the ratio of a:c and/or a:e is in the range 0.001:1 to 10:1.
- 44. (withdrawn) A method as claimed in claim 42, wherein R' is  $C_{16-18}$  saturated or unsaturated alkyl.
- 45. (withdrawn) A method as claimed in claim 42, wherein R' is selected from the group consisting of oleates, linoleate stearate, linolate, myristate, laurate and mixtures thereof.
- 46. (withdrawn) A method as claimed in claim 42, wherein component b) is selected from polyglyceryl-10-esters of fatty acids.
- 47. (withdrawn) A method as claimed in any preceding claim, wherein component d) is macrogol glycol hydrogenated castor oil.
- 48. (withdrawn) A method as claimed in any preceding claim, wherein component b) is selected from polyglyceryl-10-esters of oleic acid; component c) is selected from polyglyceryl-3-esters of oleic acid; and component d) is macrogol (1760) glycerol hydrogenated castor oil.
- 49. (withdrawn) A method as claimed in any preceding claim, further comprising excipients to modify the physical, chemical, microbial stability, organoleptic or physical processing properties of the formulation.
- 50. (withdrawn) A method as claimed in any preceding claim, wherein component a) is selected from cyclosporins cyclosporine A, cyclosporine D or cyclosporine G, wherein the ratio of components a:c+e is 1.001:1 to 1.5:1.

- (withdrawn) A method as claimed in any preceding claim, 51. wherein component a) is selected from taxanes, especially docetaxel or paclitaxel, wherein the ratio of components a:c+e is 0.001:1 to 1.5:1.
- 52. (withdrawn) A method as claimed in any preceding claim, wherein component a) includes at least one compound selected from the group comprising cyclosporins and at least one compound selected from the group comprising taxanes.
- 53. (new) A formulation according to claim 2, which contained in gelatin capsule.